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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/752,899

12/29/2000

Frank J. Bunick

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9623

7590

10/23/2006

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/752,899	Applicant(s) BUNICK ET AL.	
	Examiner Lakshmi S. Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 8-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No.: _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of RCE dated 8-2-06 is acknowledged.

Claims 1-5 and 8-13 are present in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8-2-02 has been entered.

The following is a new rejection:

Double Patenting

Claims 1, 4-5, 8 and 10-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,814,978 ('978) in view of US 6,270,790 ('790).

'978 claim a tablet composition comprising dextrose monohydrate, a pharmaceutically active ingredient and crospovidone. The dependent claims of '978 include the same active excipients claimed in the instant invention. Patented claims do not require fat and also lacks non-saccharide water-soluble polymers. Crospovidone of the patented claims is a cross-linked polyvinylpyrrolidone that is not water-soluble. The patented composition does not contain sucralose of instant claims.

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'790 teach chewable tablet compositions comprising an active ingredient, a compressible carbohydrate, sweetener, flavor and other customary ingredients (table in col. 5). Among the sweeteners, '790 teach sucralose (col. 5, lines 13-21). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to include sweeteners such as sucralose in the chewable tablet compositions of '978 because '790 teach the above sweeteners as customary additives imparting taste to the tablets. Accordingly, a skilled artisan would have included an optimum amount of sucralose depending on the desired sweetness of the tablet.

Claim Rejections - 35 USC § 103

Claims 1-5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,270,790 ('790) to Robinson et al in view of US 4,684,534 to Valentine.

'790 teach a compressed, chewable tablet preparation comprising at least one active ingredient, a carbohydrate and binder (abstract). The active ingredients of '790 include acetaminophen (col. 2, L 54-47). Among the water disintegrable and compressible carbohydrate, '790 teach dextrose (col. 2 and examples) and the binders include microcrystalline cellulose, polyvinyl pyrrolidone etc., all of which are claimed in the instant application (col. 2 and examples). The examples of '790 do not include fat and therefore, meet the claimed limitations. '790 further teach addition of a sweetener such as sucralose, aspartame etc., to the composition (col. 5, L 13-22). The examples of '790 include aspartame. However, the reference clearly teaches that the sweetener

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can be chosen from among sucralose, aspartame, saccharin etc., and accordingly substituting one sweetener for the other and in an appropriate amount in the absence of any unexpected result would have been within the scope of a skilled artisan. While instant claim 11 recites, "substantially free of microcrystalline cellulose", instant claim 12 requires the same compound. Accordingly, it appears that the presence or the absence of the above compound is not critical to the instant composition.

'790 differ from the instant claims in the absence of dextrose monohydrate and instead teach dextrose.

Valentine teaches a chewable tablet composition comprising active agents such as antacids, analgesics etc., and excipient base materials such as carbohydrate based agglomerate materials including dextrose, dextrose monohydrate, fructose, sucrose etc., which are held together by small quantities of binding materials such as maltodextrin (col. 2-3). The carbohydrate agglomerates are in the size range of 20 to 100 microns (col. 9, lines 20-42). Valentine teaches at least 25% by weight of the carbohydrate agglomerate and in particular, claim 3 recites 90% to 99% by weight for a quick melting tablet. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that the particulate agglomerated carbohydrates such as dextrose or dextrose monohydrate are equally effective for compressibility. A skilled artisan would have employed particulate dextrose or dextrose monohydrate in the tablet composition '790 because Valentine suggests that the carbohydrates enable the tablets to be highly compressible and also the tablets readily dissolve in minimal amounts of water in the mouth thus quickly liquefying of the active

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agent. With respect to the ratio of dextrose monohydrate and sucralose, one of an ordinary skill in the art would have optimized the amounts or ratios of components of the chewable tablets depending on the sweetness of the tablet desired.

Claims 1, 3-5 and 8-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,667,050 to Boissonneault et al ('050) in view of US 4,684,534 to Valentine.

'050 teach a chewable tablet composition comprising an active ingredient and carriers such as dextrose, microcrystalline cellulose, polyvinylpyrrolidone etc (all of which are claimed in the instant) and sucralose (examples). The examples of '050 contain sucralose as a sweetener. '050 teach the same binders and disintegrants that are also claimed in the instant invention but fail to teach dextrose monohydrate.

Valentine teaches a chewable tablet composition comprising excipient base materials such as carbohydrate based agglomerate materials including dextrose, dextrose monohydrate, fructose, sucrose etc., which are held together by small quantities of binding materials such as maltodextrin (col. 2-3). The carbohydrate agglomerates are in the size range of 20 to 100 microns (col. 9, lines 20-42). Valentine teaches at least 25% by weight of the carbohydrate agglomerate and in particular, claim 3 recites 90% to 99% by weight for a quick melting tablet. Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made that the particulate agglomerated carbohydrates such as dextrose or dextrose

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monohydrate are equally effective for compressibility. A skilled artisan would have employed particulate dextrose or dextrose monohydrate in the tablet composition '050 because Valentine suggests that the carbohydrates enable the tablets to be highly compressible and also the tablets readily dissolve in minimal amounts of water in the mouth thus quickly liquefying of the active agent. With respect to the ratio of dextrose monohydrate and sucralose, one of an ordinary skill in the art would have optimized the amounts or ratios of components of the chewable tablets depending on the sweetness of the tablet desired.

Response to Arguments

Applicant's arguments with respect to claims 1-5 and 8-13 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Primary Examiner
Art Unit 1615

October 12, 2006